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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,836	02/05/2004	J. Christopher Flaherty	TRNSV-044G	8515

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MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
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EXAMINER

KISH, JAMES M

ART UNIT	PAPER NUMBER
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3737

NOTIFICATION DATE	DELIVERY MODE
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05/28/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No. 10/773,836	Applicant(s) FLAHERTY ET AL.	
	Examiner JAMES KISH	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-51 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/5/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

The abstract of the disclosure is objected to because it is directed to the apparatus and not the method. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claims 24-25, 28, 36, 38-40 and 43-51 are objected to because of the following informalities:

Claims 24-25 are objected to because it appears to not have been completely written. In addition to not being completed, claim 25 is missing a word on the last line, "contact with the ... but does not contact with vessel."

Claim 28 is objected to because a distance between the stabilizer and the penetrator is defined by an undefined dimension, i.e., the diameter of the catheter.

Claim 36 is objected to because it is identical to unfinished claim 24.

Claims 38-40 are objected to because "the at least one penetrator direction marker" lacks antecedent basis. The Examiner believes the dependencies of these claims should be changed to claim 37.

Claims 43-50 are objected to because the preambles are inconsistent with the claims from which they depend.

Claims 46 and 47 are objected to because it is unclear what "TIPS" and "TEPS" stand for in the claims. These acronyms should be defined within the claims.

Claim 51 is objected to for claiming dimensions of the vessel based on the diameter of the catheter body.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,726,677.

Although the conflicting claims are not identical, they are not patentably distinct from each other because, while they fail to have identical wording, the subject matter is identical. See both sets of claims for further clarification.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 23 and 51 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 23 claims that the vessel is curved.

Claim 51 claims proportions of the vessel based on the catheter body.

In both of these claims, the vessel is not part of the invention and is nonstatutory subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-21, 26-28, 35 and 50-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishihara et al. (US Patent No. 4,950,267) – herein referred to as Ishihara. Ishihara discloses a laser beam treatment device. Figure 2 illustrates the system that is used for the methods of delivering such treatment. Catheter body **3** contains a tissue penetrator **12**, the imaging device **13** is able to orient the catheter, and balloon **17**

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stabilizes the catheter body. This is also illustrated in Figure 3 with similar labeling.

Column 3, line 52 through column 4, line 18 describes the procedure and the use of each of these portions of the device as they are claimed in claim 19.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-23, 33 and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishihara as applied to claim 19 above, and further in view of Edwards et al. (US Patent No. 5,366,490) – herein referred to as Edwards. Ishihara discloses a catheter body **3** contains a tissue penetrator **12**, the imaging device **13** is able to orient the catheter, and balloon **17** stabilizes the catheter body. This is also illustrated in Figure 3 with similar labeling. Column 3, line 52 through column 4, line 18 describes the procedure and the use of each of these portions of the device as they are claimed in

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claim 19. However, Ishihara only utilizes a single balloon for stabilization. Edwards teaches a medical probe comprising a catheter having a stylet guide housing with one or more stylet ports for directing the stylet through intervening tissue at a preselected, adjustable angle to a target tissue. The catheter can include one or more inflatable balloons located adjacent to the stylet port for anchoring the catheter (see Abstract). See Figures 1-3 for illustrations of the balloon configurations. Positioning of the guide is determined via ultrasonic imaging (column 6, lines 54-60). It would have been obvious to one of ordinary skill in the art to incorporate two balloons, as taught by Edwards, in the methods of Ishihara to provide better stabilization based on the torque that would be occur with the single expandable balloon as described by Ishihara.

Claims 24-25, 29, 32, 34, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishihara as applied to claim 19 above, and further in view of Abele (US Patent No. 5,860,974). Ishihara discloses a catheter with a tissue penetrator, the imaging device is able to orient the catheter, and a balloon that stabilizes the catheter body. However, Ishihara does not explicitly teach that blood may continue to flow while the balloon is expanded. Abele teaches an expandable member in connection with a catheter. The expandable member may be of many configurations, including a balloon (Figures 7-9), four wires at right angles to each other (Figures 10-11), a twisted assortment of flexible members (Figures 12-13) or a helical configuration of wires (Figures 14-15). In the balloon type expandable device, Abele teaches that one may use a fluoroscopic contrast agent (column 2, lines 57-61). It is obvious to one of ordinary

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skill in the art that a wire basket is a functional equivalent to an expandable balloon and would be an obvious matter of design choice to choose a balloon when it is desirable to, for example, occlude the vessel during treatment, or to choose one of the wire configurations if it is desirable to allow blood to continue to flow.

Regarding claim 25, Figure 8 of Abele illustrates that a balloon may be filled halfway and it would be obvious to one of ordinary skill in the art that an operator would be capable of filling the balloon of Ishihara halfway if such inflation parameters were desirable for the procedure being performed.

Regarding claims 29, Abele teaches that a wire basket is a functional equivalent to an expandable balloon. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made that the penetrator could be moved to a location that is surrounded by the stabilizing device and would allow the penetrator to perform the operation unaffected by the stabilizer. Therefore, it would be a matter of design choice to move the penetrator's exit port within the stabilizer. *See In re Japikse*, 86 USPQ 70.

Claims 30-31, 33 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishihara as applied to claim 19 above, and further in view of Faxon et al. (US Patent No. 5,464,395) – herein referred to as Faxon. Ishihara discloses a catheter with a tissue penetrator, the imaging device is able to orient the catheter, and a balloon that stabilizes the catheter body. However, Ishihara does not describe the stabilizer as being non-concentrically about the catheter body. Faxon teaches a

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catheter for delivering agents via a tissue penetration means and utilizing a stabilizing balloon (see Figure 1). Faxon describes several different embodiments of the balloon's configuration around the catheter body, including that illustrated in Figures 1 and 3, Figures 12 and 13, and Figures 17-19 (which is similar to that of Ishihara). It would have been an obvious matter of design choice to selecting one of these specific balloon configurations over the other, as Faxon illustrates that each are equally as capable of performing the desired function.

Regarding claim 49, Faxon teaches that the penetrating portion may deliver a therapeutic drug (column 3, lines 40-60).

Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishihara as applied to claim 19 above, and further in view of Buelna (US Patent No. 5,209,749). Ishihara discloses a catheter with a tissue penetrator, the imaging device is able to orient the catheter, and a balloon that stabilizes the catheter body. However, Ishihara does not teach an external imager for orienting the device. Buelna teaches a catheter assembly, which comprises a catheter with a balloon. A fluoroscopic image is used to orient the device based on a radiopaque marker carried by the catheter. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize an external imaging unit, such as the fluoroscopic method taught by Buelna, with the system of Ishihara, in order to properly align the device prior to the application of therapy as a functional equivalent to the optical imaging method taught by Ishihara.

It would be an obvious variant to position the marker at any location on the stabilizer that would allow the user to align the penetration device, whether that be on the same side as the penetrator or on the opposite side from the penetrator.

Claims 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishihara alone. Ishihara discloses a catheter body **3** contains a tissue penetrator **12**, the imaging device **13** is able to orient the catheter, and balloon **17** stabilizes the catheter body. Ishihara teaches an optical imaging portion of the device that is used to align a viewing window, which is located on the same side of the catheter as the penetrator, for alignment purposes (column 3, lines 1-23). While not explicitly stating a penetrator direction marker, the window itself marks the direction of penetration. Furthermore, while Ishihara discusses the optical imaging portion, it is obvious that a lumen within the catheter is required to carry the illumination light and the received signal to a viewing apparatus (see **19** of Figure 1).

Claims 43-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishihara as applied to claim 19 above, and further in view of Seward et al. (US Patent No. 5,345,940) – herein referred to as Seward. Ishihara discloses a catheter with a tissue penetrator, the imaging device is able to orient the catheter, and a balloon that stabilizes the catheter body. However, Ishihara fails to disclose the use of this catheter system with the specific procedures claimed in claims 43-48. Seward teaches a catheter with a working tool **56** or **84** (column 7, lines 11-13) and an imaging device.

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Seward teaches many procedures that may be performed with such an apparatus. See column 10, line 15 through column 11, line 53. One such example is the ablation of bypass tracts (column 10, lines 45-47). While Seward, like Ishihara, does not explicitly teach the specific procedures provided in the claims of the current application, Seward states "It is anticipated that intravascular, transvascular, and intracardiac device could be delivered through the port means... within or about the heart and blood vessels of the body (column 11, lines 36-39)." Also, "The catheter **20** will evolve into the ultimate interventional system (column 11, lines 67-68)." As well as, "There are multiple other and yet-to-be-determined applications (column 11, lines 49-50)." Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a catheter such as Seward, and also Ishihara's catheter which further improves upon Seward's by administration of a stabilizing balloon (Seward is motivated to incorporate such new technologies at column 11, lines 31-33) in order to perform bypass surgeries for the purposes of revascularization of adjacent blood vessels. This would be obvious to one of skill in the art to incorporate coronary revascularization, TIPS, TEPS and/or the creation of arterio-venous fistulas.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art
Unit 3737

JMK